

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

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MSP CORPORATION, a Minnesota corporation,

**Civil No. 07-CV-2301 (MJD/SRN)**

Plaintiff,

vs.

**DECLARATION OF NICHOLAS C.  
MILLER**

WESTECH INSTRUMENTS, INC., a Georgia corporation; WESTECH INSTRUMENT SERVICES LTD., a United Kingdom corporation; and WESTECH INSTRUMENT HOLDINGS, PLC, a United Kingdom corporation,

Defendants.

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**Nicholas C. Miller**, declares as follows:

1. I am a chemical engineer with significant experience testing and researching inhaled devices. I spent 17 years at 3M in work related to its inhalation drug products. In the early 1990's, I left 3M to pursue my own business opportunities in this field. I founded Nephele Enterprises, a company based in Minnesota that provides apparatus and equipment for testing and developing inhalers. I have extensive knowledge regarding the development and testing of inhaler devices, including the needs of the pharmaceutical and research companies that work in this field.

2. In the late 1990's, several pharmaceutical companies organized a consortium for the purpose of developing a new impactor. Companies seeking regulatory approval of new inhalers were facing increasing pressure from government regulators about the

validity and accuracy of the measurements performed with impactors. Manufacturing standards for the old Andersen Impactor were inadequate for pharmaceutical applications. Differences between these devices can produce varied measurements, prompting regulators to question how particular impactors had been calibrated, operationally qualified, and so forth. The consortium wanted to develop a single impactor that would produce consistent results and minimize regulatory concerns about testing data. Additionally, the companies needed a device that would be easier to use than the Andersen Impactors, would be highly accurate, and would be capable of testing at different flow rates.

3. Many companies submitted proposals to the consortium seeking to develop the new impactor. The consortium selected MSP Corporation based on the reputation of Virgil Marple, one of MSP's founders. Professor Marple was internationally regarded as perhaps the foremost expert in the world on the technology used in impactors. Professor Marple and I had already collaborated on several innovations in impactor technology.

4. In a consulting capacity, I assisted MSP with the development of the new impactor that was ultimately called the Next Generation Impactor. The consortium was heavily involved in the development of the Next Generation Impactor. MSP regularly presented the consortium with design decisions and options. Prototypes of the Next Generation Impactor were given to members of the consortium for testing and evaluation. Input from the consortium was used to ensure that the NGI device met expectations for ease of handling, automation, and reliability.

5. The consortium funded a calibration program for the Next Generation Impactor to establish its accuracy and precision. The consortium hired the University of Minnesota's particle calibration laboratory to conduct the calibration of the Next Generation Impactor. Members of the consortium actively monitored and participated in this calibration process to ensure confidence in the results. The Next Generation Impactor exceeded all expectations for accuracy and reliability, and the test results were instrumental in the Next Generation Impactor receiving the consortium's endorsement.

6. With the consortium's endorsement, the Next Generation Impactor has become accepted as a reliable and accurate measurement device. It produces uniform measurements between devices, and MSP's impactor has fulfilled the consortium's need to eliminate uncertainty regarding test results. The Next Generation Impactor has been subject to much more calibration and testing than any other impactor, and it is now accepted by government agencies as authoritative.

7. The consortium's endorsement of the Next Generation Impactor is a critical seal of approval that customers rely on when purchasing an impactor. That endorsement indicates that the Next Generation Impactor has been rigorously tested and vetted and that it is relied on by the leading pharmaceutical companies in the world. The consortium also wanted the benefit of one and only one impactor to be used to measure inhaler dosages. Reliance on one model eliminates measurement variability and increases the confidence that researchers and regulators place in testing data. The consortium favored a single version of the impactor. Customers rely on the consortium's endorsement of the Next Generation Impactor as that device.

8. MSP manufactures the Next Generation Impactor with highly stringent quality controls. It has strenuously worked to ensure a manufacturing process capable of state-of-the-art production of identical impactors meeting the precise specifications for the Next Generation Impactor. MSP has a well-earned reputation for quality.

9. The Next Generation Impactor name, color, and appearance of the device are associated with MSP. In particular, customers value MSP's collaboration with the consortium, its development of an impactor endorsed by the consortium, and its reputation for manufacturing consistent and reliable devices. Based on these considerations, nearly every customer buying an impactor for the research of new inhaled drug products now purchases the Next Generation Impactor device.

10. I have received email from Westech advertising its new impactor. That email was sent to me here in Minnesota. When I saw the pictures of Westech's impactor, I was shocked at the extent to which it appeared identical to the Next Generation Impactor device. In fact, in addition to copying every identifiable feature of MSP's impactor, Westech's version was even painted the same color. Based on the extent of Westech's copying, it was obvious that Westech intended to mislead consumers about the origin of its impactor. There is a real risk that customers will mistakenly purchase Westech's impactor believing it to be the Next Generation Impactor made by MSP.

11. I am concerned about the introduction of a new impactor that looks identical to the Next Generation Impactor device. Westech's impactor has not been subject to the same tests and calibrations. I highly doubt that Westech's manufacturing controls are anything similar MSP's in-process quality controls. The introduction of Westech's impactor

may undermine the confidence that researchers and regulators have placed in the Next Generation Impactor device.

12. Customers want the impactor that has been tested, validated, and widely accepted. Customers value the consortium's endorsement of the Next Generation Impactor device and its widespread acceptance. Customers will be misled if they buy the Westech impactor without realizing that it lacks all of these benefits.

I declare under penalty of perjury that the foregoing is true and correct.

June 4, 2007

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*s/ Nicholas C. Miller*  
Nicholas C. Miller

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